U.S. Food and Drug Administration

Safety

Albuterol Sulfate Inhalation Solution 0.083%, 3 mL Unit Dose Vials: Recall - Mislabeled Unit Dose Vials

[Posted 01/03/2011]

AUDIENCE: Family Practice, Pharmacy, Consumer

ISSUE: The Ritedose Corporation is conducting a voluntary recall of 0.083% Albuterol Sulfate Inhalation Solution, 3 mL in 25, 30, and 60 unit dose vials. This product is being recalled because the 2.5 mg/3 mL single use vials are embossed with the wrong concentration of 0.5 mg/ 3 mL and therefore, represents a potential significant health hazard. Only the unit dose vials are incorrectly embossed as containing 0.5 mg/3 mL. The correct concentration of 2.5 mg/3 mL is labeled on the primary foil overwrap pouches and shelf cartons. Administration of this defective product could result in a range of potential health effects that spans from temporary and medically reversible to life threatening and death.

There is significant concern that health professionals who read the incorrect embossed concentration may upwardly adjust the volume of product used resulting in an administered amount that is 5 times the recommended dose. In the hospital setting, the vials are often not accompanied by the rest of the packaging, making it more likely that such a dosing error could occur. Significant overdosing of a patient could lead to signs and symptoms of albuterol toxicity, which includes tremors, dizziness, nervousness, headache, seizures, angina, high blood pressure, low potassium levels, and rapid heart rates up to 200 beats/minute.

BACKGROUND: This product is a prescription inhalation solution, administered via nebulization, for the treatment and maintenance of acute asthma exacerbations and exercise induced asthma in children and adults. The product is packaged as a single use unit dose vials in a protective foil overwrap packaged in a she carton. The following lot numbers manufactured by The Ritedose Corporation under NDC: 0591-3797-83, 0591 3797-30, and 0591-3797-60 are included in the recall: 0N81, 0N82, 0N83, 0N84, 0NE7, 0NE8, 0NE9, 0NF0, 0P12, 0P13, 0P46, 0P47, 0PF0, and 0S15. No other Albuterol formulations or products are included in this recall. This product was distributed nationwide and Puerto Rico.

RECOMMENDATION: Consumers should immediately return the affected product to the place it was obtained (i.e. doctor's office, pharmacy, etc.). Wholesalers and retailers should return the product to the address statec in the firm Press Release.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm[1]
- Download form[2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[12/30/2010 - Press Release[3] - Ritedose Corporation]

Links on this page:

1. http://www.fda.gov/MedWatch/report.htm
2. http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
3. http://www.fda.gov/Safety/Recalls/ucm238528.htm